DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

91098d

April 5, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 01 - 48

Erik Malchow
Administrator
Rural Health Services, Inc.
1425 South Broadway, Suite 271
Alexandria, Minnesota 56308

Dear Mr. Malchow:

On March 20, 2001, a representative of the State of Minnesota, acting on behalf of the Food and Drug Administration (FDA), inspected your mobile mammography facility (FDA certificate #170670). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. Based on the documentation your site presented at the time of the inspection, the following Level 1 and Level 2 findings were documented at your facility:

Level 1 Non-Compliance:

1. The system to communicate results is inadequate. Written lay summaries must be issued to all patients within 30 days regardless of the exam's mammography assessment category. This includes those exams categorized as "Incomplete—Need Additional Imaging Evaluation."

Level 2 Non-Compliances:

2. Six of six randomly reviewed mammography reports did not contain an acceptable assessment category.

A listing of the official and approved alternate wording for assessment categories is enclosed. Non-compliances were observed at four of the remote sites where your films are interpreted; details are referenced in the Post-Inspection Report that was left at your site at the conclusion of the inspection.

3. A performance verification test was not conducted after each move of the mobile system (ACR unit designation = 2; [redacted] Room = Mobile).

4. The medical physicist's survey for mobile x-ray system (ACR unit designation = 2; [redacted] = Mobile) is incomplete because the following test was inadequate: No artifact evaluation for remotely located film processors.

   Note: Under the Quality Standards, a qualified physicist must complete the artifact test. Because your operation uses remotely located film processors, the physicist would have to visit each remote location. To reduce the burden of this requirement you may wish to submit a request (under Title 21, Code of Federal Regulations, Part 900.18 [21 CFR 900.18]) for an Alternative to the Quality Standard (Alternative Standard). Such a request may propose that the test films be generated by remotely located staff and then forwarded to the physicist for review. Other alternative methods may also be proposed. Approval of an alternate standard is required prior to its implementation.

5. Failure to produce documents verifying that [redacted] Radiologic Technologist, met the continuing education requirement of having taught or completed at least 15 continuing education units in mammography in 36 months. Documents supporting 12 CEUs in 36 months were supplied.

   Individuals failing to meet either the "Initial" and/or "Continuing" MQSA requirements must immediately cease performing mammography independently. Conditions for "Direct Supervision" of unqualified personnel are specified in regulation and formal FDA policy. Policy references may be found at the Internet address below. For the performance of a mammography examination, direct supervision means that the supervisor is present to observe and correct, as needed, the performance of the trainee. This requires that the supervisor be in the examination room itself during the time the examination is being conducted.

The specific problems noted above appeared on your MQSA Facility Inspection Report which was issued to your facility following the close of the inspection.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

It is necessary for you to act on these matters immediately. Please explain to this office in writing within 15 working days from the date you received this letter;

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations; equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures if the findings relate to quality control or other records.

Please submit your response to Thomas W. Garvin, Radiological Health Specialist, Food and Drug Administration, 2675 No. Mayfair Road, Suite 200, Milwaukee, WI 53226-1305.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the internet at *http://www.fda.gov/cdrh/mammography/index/html.*

If you have specific questions about mammography facility requirements or about the content of this letter please feel free to phone Mr. Garvin at (414) 771-7167 ext. 12.

Sincerely,

Cheryl A. Bigham
Acting Director
Minneapolis District

TWG/ccl

Enclosure

xc: [redacted]
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